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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,488	01/15/2004	David G. Gorenstein	UTMB:1019	5963

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CHALKER FLORES, LLP  
2711 LBJ FRWY  
Suite 1036  
DALLAS, TX 75234

EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/758,488	<b>Applicant(s)</b> GORENSTEIN ET AL.	
	<b>Examiner</b> T. D. Wessendorf	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-96 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 1-17 and 37, drawn to an isolated thioaptamer.

Group II, claims 18-22, drawn to a method of producing a mature thioaptamer and mature thioaptamer product.

Group III, claims 23-31, drawn to a method of mediating gene silencing of a target gene in a cell or organism.

Group IV, claims 32-34, drawn to a knockdown cell or organism.

Group V, claims 35-36, drawn to a method of examining the function of a gene in a cell or organism and a method of assessing whether a gene product is a suitable target for drug discovery.

Group VI, claims 38-44, drawn to a method of identifying target sites within an mRNA.

Group VII, claims 45-60, drawn to a combinatorial aptamer library with backbone modifications.

Group VIII, claims 61-63 (note there are two claims 62.

Misnumbered claim 62 has been renumbered claim 63),

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drawn to a thioaptamer combinatorial library comprising a unique mix of modified and unmodified nucleotides.

Group IX, claims 64-83 (misnumbered as claims 63-82), drawn to a method for reducing the expression of a gene in a cell.

Group X, claims 84-93 (misnumbered as claims 83-92), drawn to a method for attenuating expression of a target gene in cultured cells comprising using RNA thioaptamer.

Group XI, claims 94-96 (misnumbered 93-95), drawn to a method for attenuating expression of a target gene in a mammalian cell using a thioaptamer.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, IV, VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally different compounds that have different functions/effects. For example, the isolated

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thioaptamer of Group I and its pharmaceutical composition is structurally distinct from Group VII or VIII combinatorial library comprising of more than one aptamer or from the knockout gene compound.

Inventions II, III, V, VI, IX, X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to distinct methods each using distinct components and/or process steps that produces different results/ compounds with different effects and/or functions. For example, the method of Group I is drawn to producing a mature thioaptamer that is distinct from the method of Group III of mediating gene silencing of a target gene in a cell. Group V relates to determining the function of a gene or a gene product suitability as a target for drug discovery.

Inventions (I, IV, VII and VIII) and (II, III, V, VI, IX, X and XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to distinct and

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different statutory subject matter i.e., different methods and structurally different compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Groups II-XI, specifically the journal literature searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Group I is elected, applicants are to elect a single species of:

Thioaptamer as recited in claim 12.

If Group IX is elected, applicants are to elect a single species from A and B i.e., one species from A and one from B as follows:

A. Thioaptamer as recited in claim 71 (formerly claim 70). Note claim 72 (originally claim 71) is unclear as to the species being claimed and claiming "...about 70 nucleotide stem-loop RNA" as the only species.

B. Target sequence as recited in claim 73 (originally numbered as claim 72). Note that a species of the genus in claim

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73 is required. For example, election of a marker is insufficient. Applicants are to elect a species of a marker.

Each of the species covered in each of the (genus) species differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 18, 23, 32, 35, 38, 45, 61, 64, 84 and 94 are generic.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant

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must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

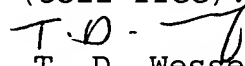


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

November 14, 2005